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Purified fatty acids for endometriosis clinical trial

Submission date
01/05/2017

Recruitment status
No longer recruiting

Registration date
30/05/2017

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Endometriosis is a common condition where tissue that behaves like the lining of the womb (endometrium) is found in other parts of the body. It affects 6-10% of women and causes severe pelvic pain. Endometriosis can be treated surgically or medically. However, symptoms often come back after surgery and the currently available medical treatments are hormones which have undesirable side effects and are contraceptive. Omega-3 purified fatty acid (PUFA) supplements may reduce endometriosis-associated pain, have minimal side effects and no effects on fertility. The aim of this small study is to assess the feasibility of conducting a larger study of PUFA for endometriosis-associated pain.

Who can participate?
Patients aged 18-50 with endometriosis

What does the study involve?
Participants are randomly allocated to receive soft gelatin capsules containing either omega-3 purified fatty acids (fish oil) or olive oil, and are advised to take two capsules per day, one in the morning and one in the evening for 8 weeks. Pain is measured at the start and end of the study and blood samples are collected to measure fatty acid levels.

What are the possible benefits and risks of participating?
PUFAs are a dietary supplement and may reduce endometriosis-associated pain. They have minimal side effects and no effects on fertility.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
October 2013 to May 2017

Who is funding the study?
University of Edinburgh (UK)

Who is the main contact?
1. Mrs Ann Doust (public)
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2. Prof. Andrew Horne (scientific)

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
2013-004938-15

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 4

Study information

Scientific Title
PurFECT: PURified Fatty acids for Endometriosis Clinical Trial: a randomised controlled trial

Acronym
PurFECT

Study objectives
Endometriosis (womb lining outside the womb) affects 6-10% of women and is associated with debilitating chronic pelvic pain. It costs the UK >£2.8 billion per year in loss of productivity. Endometriosis is managed surgically or medically. However, ~75% symptoms recur after surgery and available medical treatments ('anti-hormones') have undesirable side effects and are contraceptive. Omega-3 purified fatty acids (PUFA) have been shown in animal models to reduce factors that are thought to lead to endometriosis-associated pain, have minimal side effects and no effects on fertility. The trialists plan to perform a feasibility study to inform planning of a future multicentre trial to evaluate the efficacy of PUFA in the management of endometriosis-associated pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 01, 02/02/2016, ref: 16/SS/0010

Study design
Randomised controlled double-blind feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Endometriosis-related pain

Interventions
Participants are randomised to receive either omega-3 purified fatty acids (fish oil) or olive oil soft gelatin (placebo) capsules, with a dose of 1000 mg each, and advised to take two capsules per day, one in the morning and one in the evening for 8 weeks. The outcomes are measured at baseline and at the end of the study (i.e., 8 weeks).

Intervention Type
Supplement

Primary outcome measure
1. The proportion of screened women who are eligible for the trial
2. The proportion of eligible patients randomised into the study
3. The proportion of randomised patients who take the supplement and complete questionnaires at final follow up

The outcomes will be measured at baseline and at the end of the study (i.e., 8 weeks).

Secondary outcome measures
The remaining outcomes will be used to refine the research methodology of a future large RCT:
1. Pain, measured using the Numerical Rating Score (NRS) collected via text message during the screening phase (-1 to -4 weeks) and last 4 weeks (weeks 5-8) of the treatment phase
2. Eicosapentaenoic acid, arachidonic acid and docosahexaenoic acid concentrations measured from peripheral venous blood samples at baseline and 8 weeks
3. Quality of life, measured using SF-12 at baseline and 8 weeks
4. Pain, measured using the Brief Pain Inventory (BPI) at baseline and 8 weeks
5. Pain catastrophizing, measured using the Pain Catastrophising Questionnaire (PCQ) at baseline and 8 weeks
5. Pain, measures using the PainDETECT™ questionnaire at baseline and 8 weeks
6. Sexual activity, measured using the Sexual Activity Questionnaire (SAQ) at baseline and 8 weeks
7. Fatigue, measured using the Brief Fatigue Inventory (BFI) at baseline and 8 weeks
8. General health, measures using the General Health Questionnaire -12 (GHQ-12) at baseline and 8 weeks
9. Work and productivity activity impairment, measured using the Work and Productivity Activity Impairment Questionnaire- Specific Health Problem version 2.0 (WPAI-SHP) at baseline and 8 weeks
10. Acceptability of proposed methods of recruitment, randomisation, treatments and questionnaires, measured using a questionnaire at 8 weeks

Overall study start date
28/10/2013

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Aged 18-50 years
2. Known endometriosis diagnosed from previous laparoscopy
3. Pain of at least 3 months duration located in the true pelvis
4. Worst pain score ≥4 over 4 weeks as measured by Numerical Rating Score (NRS)
5. Ability to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
40

Total final enrolment
33

Key exclusion criteria
1. Unable to take/allergic to fish/PUFA/peanuts/soyabean
2. Insulin dependent diabetes
3. Pregnant
4. Taking contraindicated medications (anticoagulants)
5. Breastfeeding

Date of first enrolment
30/06/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
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Sponsor information

Organisation
University of Edinburgh and NHS Lothian

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Sponsor type
University/education

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
University/education

Funder Name
University Of Edinburgh

Alternative Name(s)
Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The target is to use the clinical study report for publication and presentation at scientific meetings.

Intention to publish date
01/05/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2018		Yes	No
Results article	results	17/01/2020	20/01/2020	Yes	No
Protocol file	version 2.0	25/01/2016	14/06/2023	No	No
HRA research summary			28/06/2023	No	No